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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/384,811	08/27/1999	PEGGY LEMAUX	18941000710U	8311

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT PAPER NUMBER

1638

DATE MAILED: 03/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/384,811

Applicant(s)

LEMAUX ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 10 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-25 is/are pending in the application.
- 4a) Of the above claim(s) 17-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 9-16, 24 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 13.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) ☐ Other: _____.

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 10, 2002 has been entered.

Claims 1-8 are cancelled.

Claims 24 and 25 are newly added.

Claims 9-16 and 24-25 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 24-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed June 3, 2002 for claims 1-8.

Applicant's arguments filed December 10, 2002, have been fully considered but they are not persuasive.

Applicant argues that the rejection is obviated by the cancellation of claim 1-8 (reply page 2).

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The Examiner maintains that reciting that the barley plants are made by the method of claim 9 does not distinguish the currently claimed plants from the previously claimed plants, since the method of making said plants does not impart characteristics for which a written description is provided in the specification, and therefore does not overcome the rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 is indefinite in the recitation of "population". The metes and bounds of the claim are unknown as it is unclear what parameters would define a "population" of barley plants made by the method of claim 9.

Claim Rejections - 35 USC § 103

Claims 9-14 remain rejected, and claims 24-25 are rejected, under 35 U.S.C. 103(a) as being unpatentable over McElroy et al. in view of Wan et al. and Bancroft et al., for the reasons of record set forth in the office action mailed June 3, 2002.

Claims 15-16 remain rejected under 35 U.S.C. 103(a) as being unpatentable over McElroy et al. in view of Wan et al., in view of Bancroft et al., and further in view of Perera et al., for the reasons of record set forth in the office action mailed June 3, 2002.

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Applicant's arguments filed December 10, 2002, have been fully considered but they are not persuasive.

Applicant argues that at the time of the invention, one skilled in the art had no motivation to use the Ac/Ds system in barley, and would have no reasonable expectation of success, because of factors that were known in the art, namely the methylation status of the barley genome. Applicant points to the submitted declaration of Lemaux in support of this argument. Pointing to the submitted declaration, Applicant argues that it could not be reasonably expected that the Ac/Ds system could generate stable transformants in barley, stable meaning transformants in which the transposable element can be reactivated and reinsert into the genome. Applicant argues that methylation can lead to instability and sequence loss from the genome, phenomena frequently observed in barley. Applicant argues that foreign sequences can be readily distinguished from the highly GC-rich barley sequences and preferentially inactivated, resulting in gene silencing as well as instability. Applicant also notes that the Ds inverted repeats can trigger methylation induced silencing that would prevent Ds re-activation (reply pages 3-4).

Applicant additionally argues that the elements must be stably integrated into the genome, must not be genetically silenced, and must retain the ability to reinsert into the genome. Applicant argues that one skilled in the art would expect the Ac/Ds system to be inactivated in barley, given that the high methylation state of the barley genome and the methylation of foreign sequences in barley was known to frequently lead to transgene instability and/or gene silencing (reply page 4).

Applicant points out that the declaration concludes that at the time of Applicant's invention there was no reason to expect that the Ac/Ds system would be capable of generating

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stable barley transformants, no reason to expect that a Ds element would be able to reintegrate into the barley genome, and no reason to expect that the Ds element would not itself become methylated and thus incapable of excising or reintegrating into the genome (reply page 4).

Applicant's arguments are not commensurate in scope with the claims. First, the claims do not require that the Ac/Ds system generate stable transformants in barley, or that the transposable element be reactivated and reinsert into the genome. The claims require only integration of a Ds element comprising an expression cassette into the genome of a barley plant, and the introduction of a nucleic acid encoding an Ac transposase into a barley plant. The Examiner maintains that barley transformation resulting in the integration and expression of heterologous transgenes was well known in the art at the time of Applicant's invention. For example, Schulze et al. teach integration and expression of npt and gus transgenes in transgenic barley callus cells (*Physiologia Plantarum*, 1991, Vol. 82, No. 1, pp. A32), Lazzeri et al. teach integration and expression of npt and gus transgenes in transgenic barley callus cells (*Theor. Appl. Genet.*, 1991, Vol. 81, pages 437-444, see pages 440-442), Ritala et al. teach integration and expression of npt and gus transgenes in transgenic barley callus cells (*Plant Cell Reports*, 1993, Vol. 12, pages 435-440, see page 429), Stiff et al. teach integration and expression of bar and uidA transgenes in transgenic barley callus cells (*Plant Cell, Tissue and Organ Culture*, 1995, Vol. 40, pages 243-248, see pages 245-246), and Zhang et al. teach integration and expression of the npt transgene in transgenic barley callus cells (*Plant Cell, Tissue and Organ Culture*, 1995, Vol. 41, pages 125-138, see page 132). In view of the prior art, one skilled in the art would reasonably expect to be successful in integrating a Ds element comprising an

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expression cassette into the genome of a barley plant, and in introducing a nucleic acid encoding an Ac transposase into a barley plant. The prior successful use of Ac/Ds in heterologous plant systems by others, including McElroy et al. and Bancroft et al., would motivate one skilled in the art to use Ac/Ds in barley.

Second, notwithstanding the failure of the claims to require stable transformation, and despite the high methylation state of the barley genome, the Examiner maintains that stable inheritance of functional heterologous transgenes in barley was also well known in the art at the time of Applicant's invention. In addition to the previously cited reference of Wan et al., see for example Ritala et al., teaching stable inheritance of a functional npt transgene in barley (Plant Molecular Biology, 1994, Vol. 24, pages 317-325, see pages 321-323), Funatsuki et al., teaching stable inheritance of a functional npt transgene in barley (Theor. Appl. Genet., 1995, Vol. 91, pages 707-712, see pages 710-711), Koprek et al., teaching stable inheritance of functional bar and uidA transgenes in barley (Plant Science, 1996, Vol. 119, pages 79-91, see pages 85-88), Brinch-Pedersen et al., teaching stable inheritance of functional aspartate kinase and dihydrodipicolinate synthase transgenes in barley (Plant Molecular Biology, 1996, Vol. 32, pages 611-620, see pages 614-615), and Jensen et al., teaching stable inheritance of a functional β -glucanase transgene in barley (Proc. Natl. Acad. Sci. USA, 1996, Vol. 93, pages 3487-3491, see pages 3489-3490). In view of the prior art, one skilled in the art would reasonably expect to be successful in generating stable transformants in barley comprising a functional Ac or Ds transgene.

Claim Rejections - 35 USC § 101

Claims 24-25 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility, for the reasons of record set forth for claims 1-8 in the office action mailed June 3, 2002.

Claims 24-25 are also rejected under 35 U.S.C. 112, first paragraph, for the reasons of record set forth for claims 1-8 in the office action mailed June 3, 2002. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicant's arguments filed December 10, 2002, have been fully considered but they are not persuasive.

Applicant argues that the rejection is obviated by the cancellation of claim 1-8 (reply page 2).

The Examiner maintains that reciting that the barley plants are made by the method of claim 9 does not distinguish the currently claimed plants from the previously claimed plants and therefore does not overcome the rejection.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210.

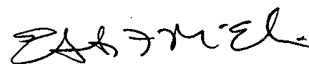
The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
March 6, 2003


ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1800